REMARKS

After entry of the amendments presented herein, claims 11, 13-14, 16-19, 22, 41, and 43-48 are pending in the application. In view of the amendments and remarks set forth herein, Applicants respectfully request allowance of all pending claims.

35 U.S.C. 112 Rejections

Claims 11, 13-14, 16-20, 22, 41, and 43-48 stand rejected under 35 U.S.C. 112. In view of the amendments set forth above, Applicants respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. 102(b) Rejections

As a preliminary matter, Applicants note that the Examiner asserts that Applicants have added new matter to the present application. Applicants disagree with the Examiner assertion. Nevertheless, Applicants have herein amended the claims to clarify that no new matter has been introduced.

Claims 11, 13, 14, 19, 20, 22, 41, and 43-48 stand rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 6,344,210, issued to Fust. Applicants traverse this rejection.

Applicants submit that the 102(e) date of Fust is later than September 1, 1999, the latest possible effective filing date of the present application, and is therefore an improper 102 reference. The application which issued as United States Patent No. 6,344,210 is a continuation-in-part of "Composition for Freshening Nostrils and Sinus Cavities," having Application Serial No. 09/585,070, filed June 1, 2000, which is a continuation-in-part of Application Serial No. 09/152,151, filed September 11, 1998, now U.S. Pat. No. 6,083,525, which is a continuation-in-part of Application Serial No. 09/123,646, filed July 28, 1998, abandoned, which is a continuation-in-part of U.S. Application Serial No. 08/644,225, filed May 10, 1996, now U.S. Pat. No. 5,785,988.

Applicants note that neither Application Serial No. 09/152,151, filed Sep. 11, 1998 nor Application Serial No. 08/644,22, filed May 10, 1996 support the claims of United States Patent No. 6,344,210. Specifically, Applicants submit that these prior applications do not support "anti-fungal means" as set forth in claims 1-10, "anti-fungal agent" as set forth in claims 11-21, "an infection preventative agent as set forth in claims 22-24, or an "anti-fungal" as set forth in claim 25. Accordingly, Applicants submit that Fust is an improper prior art reference.[1]

Claims 11, 13-14, 19, and 47 stand rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,906,811, issued to Hersh. Applicants respectfully request reconsideration and withdrawal of this rejection.

Hersh discloses use of antioxidants employed in intra-oral and aerosol delivery systems to prevent and ameliorate free radical damage induced by smoking to the oro-pharynx and upper respiratory tract. The Examiner states that Example 5 discloses the claimed invention. Applicants disagree.

Hersh does not disclose "a minor effective amount of an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt," as set forth in claims 11, 13-14, 19, and 47. Moreover, contrary to the Examiner's assertion, Applicants submit that 0.15 wt% zinc acetate, as cited by the Examiner, does not meet this feature, since 0.15 wt% is outside the 0.185 wt % to about 2.8 wt % range. Furthermore, Hersh does not teach or suggest a composition including "about 75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water and a thickening agent," as now set forth in the pending claims. The only exemplary gel compositions set forth in Hersh that include a thickening agent do not include about "75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water." Applicants thus submit that claims 11, 14, 19, 22, 41, and 43-48 are novel in view of Hersh.

[1] The filing date of a U.S. Parent Application can only be used as a 35 U.S.C. 102(e) date if it supports the claims of the issued child. In order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must (A) have a right of priority to the earlier date under 35 U.S.C. 120 and (B) support the invention claimed as required by 35 U.S.C. 112, first paragraph. MPEP 2136.03.

35 U.S.C. 103 Rejections

Claims 11, 13-14, 16-20, 41, 43-45 and 47-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh. Applicants request reconsideration and withdrawal of this rejection.

As noted above, Hersh does not teach or suggest a composition including "about 75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water and a *thickening agent*." Furthermore, Hersh does not disclose a composition including a minor effective amount of an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt and *a thickening agent* selected from the group consisting of carrageenan, sugar, guar gum, hydroxycellulose, methylcellulose, hydroxyethylcellulose, and other carbohydrates. Contrary to the Examiner's assertion, nothing in either Hersh or the present application suggests that xylitol is *a thickening agent*. Indeed, Hersh teaches away from such suggestion. Hersh specifically lists thickening agents such as chicle, xantham, arabic, karaya or tragacanth gums. Hersh separately mentions that xylitol can be used as a preferred sweetener. Thus, Hersh does not teach that xylitol is a thickening agent and teaches away from its use as such by noting xylitol's use as a sweetener but not as a thickening agent. Accordingly, Applicants submit that claim 11 and claims 14, 16-19, 41, 43-45 and 47-48 that depend therefrom are patentable over the cited art.

Claims 11, 13, 16-20, 22, 41-45, and 47-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Re. 33, 465, issued to Eby in view of ES 2095183, HCAPLUS abstract 1994:638216 and DE 3431727. Applicants respectfully request reconsideration and withdrawal of this rejection.

Eby discloses a method to reduce a duration of common colds through use of zinc gluconate topically applied to the oral mucosa. Although the reference discloses that various forms of applying the composition may be used, Eby also distinguishes itself from intranasal application of zinc compositions. *See, e.g.,* Abstract.

ES 2095183 discloses a drug delivery system that includes aqueous compositions. The aqueous compositions include 8-12% poloxamer, less than 1% of bioadhesive polymer, and

sodium chloride to obtain an isotonic final solution. Nowhere does the reference teach or suggest a composition including "a minor effective amount of an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt" or "about 75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water."

DE 3431727 generally discloses a nose spray composition that includes zinc gluconate. Nowhere does the reference teach or suggest any thickening agents or any motivation for adding thickening agents to the composition.

Claims 11, 13-14, 16-20, 41, 43-45 and 47-48 are nonobvious in view of the cited art, because no combination of the cited references teaches or suggest "a minor effective amount of an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt" or "about 75 wt % to about 99.999 wt % carrier comprising about 75 to about 99.999 wt % water and a thickening agent selected from the group consisting of carrageenan, sugar, guar gum, hydroxycellulose, methylcellulose, hydroxyethylcellulose, and other carbohydrates."

Furthermore, there is no suggestion to combine the references to form the claimed invention. The Examiner asserts that Eby does not provide a specific formulation for nasal administration and thus one would have looked to nasal delivery technology that was available before Applicants' effective filing date and that ES 2095185 teaches that its aqueous drug delivery preparation is a liquid at room temperature but gels at body temperature and adheres to the nasal mucosa, thereby providing controlled delivery of active drugs. Applicants disagree with the Examiner's analysis for several reasons. First, Eby acknowledged that intranasal zinc formulations existed at the time of his invention. Eby distinguished his invention over the intranasal compositions—stating that such compositions did not work and that his invention is an improvement over zinc-based nasal sprays. *See* Abstract and Prior Art. Thus, Eby would not motivate someone to look at nasal delivery technology. Second, even if one were motivated to look to nasal application technology, such would not necessarily lead to combining the teachings of Eby with the teaching of ES 2095185, since Eby acknowledges and references other prior art available at the time that relates to nasal application of zinc compositions, and further notes that the methods disclosed in those references were ineffective.

Nevertheless, as noted above, even if the references were combined, the combination does not teach or suggest the claimed invention. Accordingly, Applicants submit the claims are patentable over the cited art.

Non-Statutory Double Patentng

Claims 11, 13, 17-20, 22, 41, and 44-45 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over United States Patent No. 6,673,835 in view of ES 2095185 and DE 3431727. Applicants respectfully request reconsideration of this rejection in view of the arguments and amendments set forth herein.

CONCLUSION

In view of the foregoing remarks, Applicants believe that the pending claims are allowable over the cited art and Applicants therefore earnestly request allowance of all pending claims. The undersigned requests a telephone call at the telephone number listed below if, for any reason, the Examiner deems one or more of the pending claims unpatentable.

Applicants authorize and respectfully request that any extension of time fees due be charged to Deposit Account No. 19-2814. **This statement does NOT authorize charge of the issue fee**.

Respectfully submitted,

Date: 6/15/07

By: _____
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